



UNITED STATES PATENT AND TRADEMARK OFFICE

JW
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/082,691 | 02/25/2002 | Stephen Donovan | D-3018 | 5311 |
| 33197 | 7590 | 06/24/2004 | EXAMINER | |
| STOUT, UXA, BUYAN & MULLINS LLP 4 VENTURE, SUITE 300 IRVINE, CA 92618 | | | MARX, IRENE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1651 | |

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/082,691 | DONOVAN, STEPHEN |
| | Examiner Irene Marx | Art Unit 1651 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 6/1/04.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-29 is/are pending in the application.
 4a) Of the above claim(s) 10,11,13-16,20,21,28 and 29 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-9,12,17-19 and 22-27 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. _____.
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____ 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____

The amendment filed 6/1/04 is acknowledged. Claims 1-9, 12, 17-19, 22-27 are being considered on the merits.

Claims 10-11,13-16, 20-21 and 28-29 are withdrawn from consideration as directed to a non-elected invention. This application contains claims 10-11,13-16, 20-21 and 28-29 drawn to an invention nonelected with traverse in the reply filed on 1/30/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 12, 17-19, 22 -27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for an agent comprising a botulinum toxin component “conjugated with” a substance P component. From the as filed specification it is apparent that the components are covalently coupled. See, e.g., page 16, paragraph 2.

Generally, a conjugated protein is defined as a protein that contains at least one prosthetic group, i.e., an organic compound (other than an amino acid) or a metal ion that is covalently bound to a protein and serves an essential function in its activity.

Therefore, this material constitutes new matter and should be deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 12, 17-19, 22 -27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite and confusing in the recitation of an “effective amount” of an agent comprising a botulinum toxin component “conjugated” with a substance P component. It is unclear what is intended. See also the new matter rejection, *supra*. In addition, the relative amounts intended for each of the components and their relationship in the composition is not set forth with sufficient particularity. Moreover, it is apparent that by administering a sufficient therapeutic amount of botulinum toxin alone pain may be eliminated by killing the patient.

Claim 9 is vague and indefinite in the recitation of “substance P functional analogue”, since the extent of the similarity is not indicated. The function intended is uncertain. How is analogy determined?

Claims 22 through 27 are vague, indefinite and confusing in the recitation of “in an amount that will reduce pain in a patient by...”. Is this the same or different from the “therapeutically effective amount”? The amount required to reduce pain in an individual cannot be readily determined, since “pain” is dependent on the pain threshold and perception of the individual to be treated and is relative with respect to the severity of the condition and of the pain. Pain is a psychological experience with an emotional dimension. Thus it is not readily measured “based on a quantification scale”. It is at least uncertain how this “quantification scale” is to be standardized to be meaningful and to enable administration of an amount of the agent for reduction of pain in the required percentages.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 12, 17-19, 22 -27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-7, 9, 11-20 of U.S. Patent No. 6,500,436. Although the conflicting claims are not identical, they are not patentably distinct from each other because the conflicting claims are similarly directed to methods a treating pain, including neurogenic inflammation pain due to arthritis with the same composition comprising a botulinum toxin component and a substance P component to a patient.

The terminal disclaimer filed is acknowledged. However, review thereof is not yet complete.

The art rejections are withdrawn in view of applicant's amendments. The rejections will be reinstated as appropriate upon removal of the new matter introduced by the instant amendment.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Irene Marx
Primary Examiner
Art Unit 1651